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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) 026.00041 |
| <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR</p> <p>on <u>July 27, 2006</u></p> <p>Signature <u>Karla M. Weyand</u></p> <p>Typed or printed name <u>Karla M. Weyand</u></p> | | <p>Application Number 09/748,642</p> <p>Filed 12/22/2000</p> <p>First Named Inventor Thomas Albrecht</p> <p>Art Unit 1635</p> <p>Examiner J. Ashen</p> |
| <p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s).</p> <p>Note: No more than five (5) pages may be provided.</p> | | |
| <p>I am the</p> <p><input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (From PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>40,223</u> <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p><u>Karla M. Weyand</u> Signature <u>Karla M. Weyand</u> Typed or printed name <u>716-626-5380</u> Telephone number <u>July 27, 2006</u> Date</p> | | |
| <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> | | |

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| <input type="checkbox"/> | *Total of _____ forms are submitted. |
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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026.00041

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Albrecht et al.)
Serial No.: 09/748,642) Examiner: J. Ashen
Filed: December 22, 2000) Art Unit: 1635
For: INHIBITION OF CELLULAR)
PROTEASES)

)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
MS AF

Sir:

I. Error in the Rejections:

The Advisory Action dated May 10, 2006 ("advisory action") states that claims 6-8 and 14-16 are rejected under 35 U.S.C. §103 (a) for obviousness over U.S. Patent No. 5,478,727 to Roizman et al. ("Roizman"), U.S. Patent No. 5,607,831 to Henkart et al. ("Henkart"), Kido et al., Advances in Enzyme Regulation, 36:325-347 (1996) ("Kido") and de Jong et al., Antiviral Research, 39:141-162 (1998) ("de Jong"). However, it is applicants' position that no motivation is provided to combine the references in the manner cited in the advisory action.

II. Remarks to Overcome Error in the Rejections:

The disclosures of Roizman, Henkart, Kido and de Jong are discussed extensively in the prosecution history. Briefly, Roizman and Henkart relate exclusively to viral proteases. Kido relates to cellular protease involvement in enveloped animal viruses, HIV, influenza virus A and Sendai virus. de Jong relates to human cytomegalovirus and its persistence in latent form.

Roizman, Henkart, Kido and de Jong are not properly combinable. The U.S. Patent and Trademark Office ("PTO") has

provided no basis for a motivation of one skilled in the art, either in the references or in the state of the art, to make the cited combination. If one assumes, for example, that one skilled in the art was motivated to modify Roizman (which applicants submit they were not), one would have had to modify Roizman (which relates exclusively to viral proteases) to administer calpain inhibitors (which are not disclosed or suggested in Roizman) and decrease levels of functional cellular protease in the cells (which is not disclosed or suggested in Roizman). The PTO appears to rely on Kido for motivating one skilled in the art to decrease functional cellular proteases in a method of decreasing viral replication of HCMV. However, one skilled in the art would not have looked to Kido, as Kido relates exclusively to particular, specific viruses, none of which is HCMV. Further, the PTO appears to further rely on de Jong for motivation to modify Roizman (for example, see the office action dated January 27, 2006 ("office action") (page 8, second paragraph) which indicates that the basis for the cited combination is "the prior art as a whole"), to decrease viral replication of HCMV. Although not specifically stated, the implication of the PTO appears to be that one skilled in the art would have been motivated to treat HCMV in a manner similar to the treatment of HIV because de Jong teaches that HCMV may be present in persons infected with HIV. However, there is no suggestion in de Jong, or in any of the cited references, that treatment of HIV with any compound, let alone a calpain inhibitor, results in decreasing viral replication of a HCMV.

In addition, there is no motivation in any of the references, or in the state of the art, to suggest to one skilled in the art to use the calpain inhibitors of Henkart to treat anything other than HIV. Even if, assuming arguendo, that (1) a motivation to combine the references is provided, which applicants submit it is not and (2) the teaching of Roizman is as stated in the office action, which applicants submit it is not, the cited combination would only teach, at

most, a method of treating HIV infection by decreasing levels of functional cellular protease in the cells by exposing the cells to a calpain inhibitor. The fact that de Jong teaches CMV disease in HIV-infected persons being caused by reactivation of latent virus does not provide motivation to treat CMV disease in a manner similar to treatment of HIV. Applicants respectfully assert that this argument meets an "obvious to try" standard.

For the above reasons, the rejections of claims 6-8 and 14-16 under 35 U.S.C §103 as obvious over the cited references is improper and must be withdrawn.

Applicants assume that the rejection of claims 8 and 16 under 35 U.S.C. § 103 as obvious over Henkart and de Jong in view of U.S. Patent No. 6,015,787 to Potter ("Potter") is respectfully traversed because this rejection has not been repeated in the advisory action.

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

July 27, 2006
Date

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I hereby certify that this document is being deposited with the U.S. Postal Service as first class mail on 7/27/06 under 37 CFR 1.8 and is addressed to the Commissioner for Patent, PO Box 1450, Alexandria, VA 22313-1450

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Signature of Person Mailing Correspondence

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